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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/084,491	05/27/1998	PAUL A. MOORE	PF378	5606

22195 7590 02/13/2002

HUMAN GENOME SCIENCES INC
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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/13/2002

30

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/084,491

Applicant(s)

MOORE ET AL.

Examiner

Elizabeth Slobodyansky

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 23 January 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 112, 2nd.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 76-182.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

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Attachment to Advisory action (Paper #30)

The amendment filed January 23, 2002 under 37 CFR 1.116 in reply to the final rejection will be entered upon the filing of an appeal, but is not deemed to place the application in condition for allowance.

The AF amendment has overcome the 112, 2nd paragraph, rejection of claims 88, 96, 104, 112, 114-123, 125, 133, 135-144, 146, 154, 157, 165, 174 and 182.

The 101 rejection of claims 76-182 is maintained.

The 112, 1st paragraph, rejection (enablement) of claims 166-182 is maintained.

The 112, 1st paragraph, rejection (written description) of claims 166-170 and 173-182 is maintained. Claims 171 and 172 have been previously included in this rejection in inadvertent error.

Response to Arguments

Applicant's arguments filed January 23, 2002 have been fully considered but they are not persuasive.

Applicants argue that the examiner did not establish "why it is more likely than not [that] one of ordinary skill in the art would doubt (i.e."question") the truth of statement of utility" (pages 9-11, specifically sentence bridging pages 9 and 10).

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The asserted utility for t-PALP (SEQ ID NO: 2) is based on low (about 21.3%) homology to human t-PA. The examiner's position is that said utility is not credible because such homology, if it exists, absent any additional data, does not yet impart any specific function to the protein. Indeed, no specific function is putatively assigned to a protein having 99.8% identity to SEQ ID NO: 2 (form PTO-1449, reference BV, filed January 25, 2001). Since the instant specification does not disclose a credible use for t-PALP, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

Regarding the 112, 1st paragraph, written description rejection, Applicants argue that the genus of DNAs that comprise 30/50 nucleotides is sufficiently described because no "functional characteristic is claimed in the instant claims" (page 13). It appears that Applicants' arguments are concerned with a DNA comprising 30/50 nucleotides of SEQ ID NO:1 that is a fragment of SEQ ID NO: 1. However, the rejection is over a DNA of any length and composition that is not a fragment. Said DNA may not be encoding a protein or may be encoding a protein of any function. However, the identifying characteristics distinguishing the claimed genus from other molecules is not described.

Regarding the 112, 1st paragraph, enablement rejection, it appears that Applicants' arguments are concerned with a DNA comprising 30/50 nucleotides of SEQ ID NO:1 that is a fragment of SEQ ID NO: 1. However, the claims encompass any DNA

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comprising 30/50 nucleotides of SEQ ID NO:1. They argue that the above DNAs can be used "as probes for detection of the t-PALP gene and the primers to amplify t-PALP polynucleotides" (page 16). This is correct for the fragment of SEQ ID NO:1 if SEQ ID NO:1 has utility. It would constitute a single use of a fragment (see page 17). However, a probe or primer does not have utility if what is probed for does not have one. A DNA comprising 30/50 nucleotides of SEQ ID NO:1 that is not a fragment of SEQ ID NO: 1 is not enabled for the reasons stated in the Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

February 1, 2002